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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,566

Applicant(s)

STAHLER ET AL.

Examiner

MY-CHAU T. TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-54 is/are pending in the application.
- 4a) Of the above claim(s) 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-45 and 47-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/763,914.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Office Action</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application and Claims Status

1. Applicant's response filed 09/11/2006 are acknowledged and entered.
2. In the preliminary amendment filed 12/05/2003, applicants have cancelled claims 1-38, and added claims 39-54. Therefore, claims 39-54 are currently pending.

Election/Restrictions

3. Applicant has elected the following species for the elected invention (Claims 39-54) in the reply filed on 09/11/2006:
 - a. For the single specific species of support, applicant elected the support species of claim 40. All claims except claim 46 read on the elected species.
 - b. For the single specific species of compound being immobilized, applicant elected receptor building blocks. All claims read on the elected species.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claim 46 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to *a nonelected species*, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/11/2006.

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Priority

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/763,914, filed on 05/11/2001.

Information Disclosure Statement

6. The information disclosure statements (IDS) filed on 12/05/2003 and 02/16/2006 have been reviewed, and the references that have been considered are initialed as recorded in PTO-1449 forms. *Note: Applicant indicated that copies of the documents for the IDS filed 12/05/2003 were submitted in the application of 09/763,914.*

Specification

7. The disclosure is objected to because of the following informalities:
- A. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/763,914 filed 05/11/2001. However, the specific reference to the earlier filed application must be made in the instant application, i.e. a reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional

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applications. *Also, the current status of all nonprovisional parent applications referenced should be included.* Here, neither the instant specification nor the application data sheet includes the current status of the Application No. 09/763,914, which is now US Patent 7,097,974 B1.

B. It is noted that the brief descriptions of the several views of the drawing were mix within the detailed description of the invention (e.g. see specification pages 40-41). The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

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C. Specific claim number(s) are refers to throughout the instant specification, for example "Claim 1" was refers to in page 6 line 20. However, claim 1 was cancelled by the preliminary amendment filed 12/05/2003. Thus, it is best to avoid any confusion by avoiding reference to a particular claim in the specification since the claim can be amended, cancelled, and/or the numbering changed.

Appropriate correction is required.

8. Claims 39-45 and 47-54 are under consideration in this Office Action.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 53 recite the limitation that invoke the 35 U.S.C. 112, sixth paragraph, i.e. the means (or step)-plus-function claim limitation. Claim 53 states "*The method as claimed in claim 40, characterized in that the apparatus additionally comprises means for deprotection of reaction components on the support*".

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35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language “shall be construed to cover the corresponding structure...described in the specification and equivalents thereof.” “If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.” See *In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994)(in banc). Here, the instant specification fails to provide adequate structure (or material or acts) for performing the recited function claimed in claim 53. The instant specification on page 40, line 13-22, disclose known protecting groups that permit light-dependent deprotection, and on page 44, lines 7-19, the instant specification refers to ref. #32 in figure 5 as a fluidic deprotection module, i.e. two distinct structures wherein one refers to a chemical compound and the other is a structural feature of the apparatus, and both function as deprotecting the ‘*reaction components on the support*’. And as a result, claim 53 fails to satisfy the requirements of 35 U.S.C. 112, sixth paragraph, and also the requirements of 35 U.S.C. 112, second paragraph. See *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1115-18, 63 USPQ2d 1725, 1731-34 (Fed. Cir. 2002), and also MPEP § 2181(II).

Moreover, Whether a claim reciting an element in means- (or step-) plus-function language fails to comply with 35 U.S.C. 112, second paragraph, because the specification does not disclose adequate structure (or material or acts) for performing the recited function *is closely* related to the question of whether the specification meets the description requirement in 35

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U.S.C. 112, first paragraph. See *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976). Accordingly, the instant specification does not meet the description requirement in 35 U.S.C. 112, first paragraph.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 39-45 and 47-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 39 recites the limitation "receptor building blocks" in lines 6-7. There is insufficient antecedent basis for this limitation in the claim. Claim 39 first recited the limitation of "*receptors or building blocks for synthesizing polymeric receptors over a support*", and as a result, it is unclear as to which receptor does this limitation reference to. Thus, claim 39 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph. It is suggested that applicant replace the phrase "receptor building blocks" with "building block".

B. Claim 41 is vague and indefinite. Claim 41 recites "*the analyte is removed again from the support after the determination*". Step (f) of claim 39 recites the step of "*determining the analytes via their binding to the receptors immobilized on the support*", i.e. the analyte is bound to the receptors that are attached to the support. Consequently, the analyte was never removed, and claim 41 is vague and indefinite

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because it is unclear when the analyte was removed first. Thus, claim 41 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

C. The term “*synthesis/analyte*” of claim 42 and 48 that is use to further define the phrase “*determination cycles*” is vague because it unclear whether it is defining two distinct type of “*determination cycles*”, i.e. a synthesis determination cycle or a analyte determination cycle, or a hybrid type of “*determination cycles*”. As a result, claim 42 and 48 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

D. Claim 53 recite the limitation that invoke the 35 U.S.C. 112, sixth paragraph, i.e. the means (or step)-plus-function claim limitation. Claim 53 states “*The method as claimed in claim 40, characterized in that the apparatus additionally comprises means for deprotection of reaction components on the support*”. The instant specification fails to provide adequate structure (or material or acts) for performing the recited function claimed in claim 53. The instant specification on page 40, line 13-22, disclose known protecting groups that permit light-dependent deprotection, and on page 44, lines 7-19, the instant specification refers to ref. #32 in figure 5 as a fluidic deprotection module, i.e. two distinct structures wherein one refers to a chemical compound and the other is a structural feature of the apparatus, and both function as deprotecting the ‘*reaction components on the support*’. And as a result, claim 53 fails to satisfy the requirements of 35 U.S.C. 112, sixth paragraph, and also the requirements of 35 U.S.C. 112, second paragraph. See MPEP § 2181(II). Thus, claim 53 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 39 and 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirrung et al. (US Patent 5,142,854).

For *claim 39*, Pirrung et al. disclose methods and apparatus for the preparation and use of a substrate having a plurality of polymer sequences in predefined regions (see e.g. Abstract; col. 3, lines 6-38; col. 8, lines 17-19). The method comprises the steps of providing a substrate with linker molecules that is provided with a reactive functional group protected with a photoremovable protective group (refers to instant claimed step (a)); removing the photoremovable protective group on the linker molecules that are attached to the surface of the substrate of the first set of selected regions by exposing the photoremovable protective group to light using a mask to direct light from the light source to selected regions on the substrate; attaching the first monomer to the surface of the substrate by reacting the solution of first monomer with the exposed functional group on the surface of the substrate (refers to instant claimed step (b) and (c)); removing the photoremovable protective group on the linker molecules that are attached to the surface of the substrate of the second set of selected regions by exposing the photoremovable protective group to light using a mask to direct light from the light source to selected regions on the substrate; attaching the second monomer to the surface of the substrate by reacting the solution of second monomer with the exposed functional group on the surface of the

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substrate (refers to instant claimed steps (b) and (c)); repeating the steps, i.e. the removing and attaching steps, to selectively apply monomers until polymers of a desired length and chemical sequence are obtained (refers to instant claimed step (d))(see e.g. col. 3, lines 8-38; col. 8, lines 17-33 and 46-65; col. 9, line 14 thru col. 10, line 30; col. 14, line 60 thru col. 15, line 48; figs. 1-7). In addition, the method includes using the prepared substrate in screening for biological activity wherein the substrate is exposed to a solution of receptor of interest (refers to instant claimed analyte) and detecting the binding of the receptor of interest to the one or more polymers on the substrate (refers to instant claimed steps (e) and (f))(see e.g. col. 10, line 32 thru col. 11, line 7; col. 18, line 62 thru col. 19, line 16). Furthermore, Pirrung et al. disclose that the methods are automated or semi-automated, i.e. monitored and controlled by a computer (refers to instant claimed an integrated apparatus and step (c))(see e.g. col. 4, lines 23-27; col. 20, line 28 thru col. 22, line 53; col. 25, lines 34-36).

For *claims 42-45*, Pirrung et al. disclose a computer program for a binary synthesis strategy wherein an ordered strategy for parallel synthesis of diverse polymers by sequential addition of the reagents to produce a diverse polymers sequences on the substrate (see e.g. col. 9, line 20 thru col. 10, lines 15; col. 20, line 28 thru col. 22, line 53).

Therefore, the method of Pirrung et al. does anticipate the instant claimed invention.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 39 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung et al. (US Patent 5,142,854) and Fodor et al. (US Patent 5,925,525; *filing date of 04/03/1998*).

For **claim 39**, Pirrung et al. disclose methods and apparatus for the preparation and use of a substrate having a plurality of polymer sequences in predefined regions (see e.g. Abstract; col. 3, lines 6-38; col. 8, lines 17-19). The method comprises the steps of providing a substrate with linker molecules that is provided with a reactive functional group protected with a photoremovable protective group (refers to instant claimed step (a)); removing the photoremovable protective group on the linker molecules that are attached to the surface of the substrate of the first set of selected regions by exposing the photoremovable protective group to light using a mask to direct light from the light source to selected regions on the substrate; attaching the first monomer to the surface of the substrate by reacting the solution of first monomer with the exposed functional group on the surface of the substrate (refers to instant claimed step (b) and (c)); removing the photoremovable protective group on the linker molecules

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that are attached to the surface of the substrate of the second set of selected regions by exposing the photoremovable protective group to light using a mask to direct light from the light source to selected regions on the substrate; attaching the second monomer to the surface of the substrate by reacting the solution of second monomer with the exposed functional group on the surface of the substrate (refers to instant claimed steps (b) and (c)); repeating the steps, i.e. the removing and attaching steps, to selectively apply monomers until polymers of a desired length and chemical sequence are obtained (refers to instant claimed step (d))(see e.g. col. 3, lines 8-38; col. 8, lines 17-33 and 46-65; col. 9, line 14 thru col. 10, line 30; col. 14, line 60 thru col. 15, line 48; figs. 1-7). In addition, the method includes using the prepared substrate in screening for biological activity wherein the substrate is exposed to a solution of receptor of interest (refers to instant claimed analyte) and detecting the binding of the receptor of interest to the one or more polymers on the substrate (refers to instant claimed steps (e) and (f))(see e.g. col. 10, line 32 thru col. 11, line 7; col. 18, line 62 thru col. 19, line 16). Furthermore, Pirrung et al. disclose that the methods are automated or semi-automated, i.e. monitored and controlled by a computer (refers to instant claimed an integrated apparatus and step (c))(see e.g. col. 4, lines 23-27; col. 20, line 28 thru col. 22, line 53; col. 25, lines 34-36).

For *claims 42-45*, Pirrung et al. disclose a computer program for a binary synthesis strategy wherein an ordered strategy for parallel synthesis of diverse polymers by sequential addition of the reagents to produce a diverse polymers sequences on the substrate (see e.g. col. 9, line 20 thru col. 10, lines 15; col. 20, line 28 thru col. 22, line 53).

The teachings of Pirrung et al. differs from the presently claimed invention as follows:

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For *claim 41*, Pirrung et al. fail to disclose the step of removing the analyte after the determination step.

However, Fodor et al. teach the limitations that are deficient in Pirrung et al.

For *claim 41*, Fodor et al. disclose the methods and apparatus for sequencing, fingerprinting, and mapping biological polymers (see e.g. Abstract; col. 2, lines 26-33). The method includes the step of removing the target from the substrate after the analysis of the hybridization pattern of the target on the substrate (see e.g. col. 24, lines 49-63; col. 28, lines 62-67; col. 55, line 64 thru col. 56, line 7).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose the step of removing the analyte after the determination step as taught by Fodor et al. in the method of Pirrung et al. One of ordinary skill in the art would have been motivated to disclose the step of removing the analyte after the determination step in the method of Pirrung et al. for the advantage of providing an automated system that would improve the reproducibility and accuracy of sequencing biological polymers (Fodor: col. 2, lines 17-23). Moreover, Fodor et al. disclose using the methods for making an array of diverse set of polymers on a substrate described in U.S. Pat. No. 5,143,854, i.e. incorporating by reference the teaching of Pirrung et al., (Fodor: col. 8, lines 55-58). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Pirrung et al. and Fodor et al. because Fodor et al. disclose by example using the technique of Pirrung et al. to make an array of diverse set of polymers on a substrate (Fodor: col. 72, lines 41-51; fig. 12A).

Therefore, the combine teachings of Pirrung et al. and Fodor et al. do render the method of the instant claims *prima facie* obvious.

18. Claims 39, 42-45, 47, 48, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung et al. (US Patent 5,142,854) and Wrinkler et al. (US Patent 5,677,195).

For *claim 39*, Pirrung et al. disclose methods and apparatus for the preparation and use of a substrate having a plurality of polymer sequences in predefined regions (see e.g. Abstract; col. 3, lines 6-38; col. 8, lines 17-19). The method comprises the steps of providing a substrate with linker molecules that is provided with a reactive functional group protected with a photoremovable protective group (refers to instant claimed step (a)); removing the photoremovable protective group on the linker molecules that are attached to the surface of the substrate of the first set of selected regions by exposing the photoremovable protective group to light using a mask to direct light from the light source to selected regions on the substrate; attaching the first monomer to the surface of the substrate by reacting the solution of first monomer with the exposed functional group on the surface of the substrate (refers to instant claimed step (b) and (c)); removing the photoremovable protective group on the linker molecules that are attached to the surface of the substrate of the second set of selected regions by exposing the photoremovable protective group to light using a mask to direct light from the light source to selected regions on the substrate; attaching the second monomer to the surface of the substrate by reacting the solution of second monomer with the exposed functional group on the surface of the substrate (refers to instant claimed steps (b) and (c)); repeating the steps, i.e. the removing and attaching steps, to selectively apply monomers until polymers of a desired length and chemical sequence are obtained (refers to instant claimed step (d))(see e.g. col. 3, lines 8-38; col. 8, lines 17-33 and 46-65; col. 9, line 14 thru col. 10, line 30; col. 14, line 60 thru col. 15, line 48; figs. 1-

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7). In addition, the method includes using the prepared substrate in screening for biological activity wherein the substrate is exposed to a solution of receptor of interest (refers to instant claimed analyte) and detecting the binding of the receptor of interest to the one or more polymers on the substrate (refers to instant claimed steps (e) and (f))(see e.g. col. 10, line 32 thru col. 11, line 7; col. 18, line 62 thru col. 19, line 16). Furthermore, Pirrung et al. disclose that the methods are automated or semi-automated, i.e. monitored and controlled by a computer (refers to instant claimed an integrated apparatus and step (c))(see e.g. col. 4, lines 23-27; col. 20, line 28 thru col. 22, line 53; col. 25, lines 34-36).

For *claims 42-45*, Pirrung et al. disclose a computer program for a binary synthesis strategy wherein an ordered strategy for parallel synthesis of diverse polymers by sequential addition of the reagents to produce a diverse polymers sequences on the substrate (see e.g. col. 9, line 20 thru col. 10, lines 15; col. 20, line 28 thru col. 22, line 53).

For *claims 51*, Pirrung et al. disclose that the substrate include material such as glass (see e.g. col. 11, lines 29-50).

The teachings of Pirrung et al. differs from the presently claimed invention as follows:

For *claims 47, 48, 50*, Pirrung et al. fail to disclose that the support comprises a large number of channels wherein a large number of different receptors are immobilized.

However, Winkler et al. teach the limitations that are deficient in Pirrung et al.

For *claims 47, 48, 50*, Winkler et al. disclose methods and devices for forming large arrays of polymers on a substrate (see e.g. Abstract; col. 2, lines 15-23, and 55-62). In one method, the method comprises the steps of providing a block having a series of channels that is placed in contact with a substrate; using a delivery system flow selected reagents to one or more

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of a series of apertures connected to the channels to fill the channels and "striping" the substrate with a first reagent; coupling a first group of monomers onto the substrate wherein the first group of monomers need not be homogenous, i.e. a monomer A may be placed in a first group of the channels, a monomer B in a second group of channels, and a monomer C in a third group of channels; repeating the flowing and coupling steps with a second reagent and coupling a second group of monomers to different regions of the substrate. The process is repeated until a diverse set of polymers of desired sequence and length is formed on the substrate (see e.g. col. 2, lines 31-55; col. 10, line 27 thru col. 13, line 44; figs. 2 and 6-11). In addition, the method includes using the prepared substrate in screening for biological activity wherein the substrate is exposed to a solution of receptor of interest (refers to instant claimed analyte) and detecting the binding of the receptor of interest to the one or more polymers on the substrate (see e.g. col. 17, line 58 thru col. 18, line 6; col. 29, line 52 thru col. 30, line 64). Furthermore, Winkler et al. also disclose that the substrate comprises a series of microchannels (see e.g. col. 2, lines 56-62).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose that the support comprises a large number of channels wherein a large number of different receptors are immobilized as taught by Winkler et al. in the method of Pirrung et al. One of ordinary skill in the art would have been motivated to disclose that the support comprises a large number of channels wherein a large number of different receptors are immobilized in the method of Pirrung et al. for the advantage of providing independent control of the reaction conditions at different activated regions such that the reactant concentrations and other parameters can be varied independently from reaction site to reaction site (Winkler: col. 8, lines 48-56). Moreover, Winkler et al. disclose using the "light directed" methods described in

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U.S. Pat. No. 5,143,854, i.e. incorporating by reference the teaching of Pirrung et al., for making an array of diverse set of polymers on a substrate (Winkler: col. 8, lines 22-39). Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Pirrung et al. and Winkler et al. because Winkler et al. disclose by example the success of the method using support with channels for synthesizing different polymers on the substrate (Winkler: col. 29, line 51 thru col. 30, line 64).

Therefore, the combine teachings of Pirrung et al. and Winkler et al. do render the method of the instant claims *prima facie* obvious.

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 39-45, 47, 48, and 50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31 and 37-45 of copending Application No. 10/399,450, i.e. a preliminary amendment was filed in this application wherein claims 1-30 were cancelled and claims 31-60 were added. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and copending Application No. 10/399,450 claimed a method for integrated synthesis and analyte determination on a support comprising similar method steps and uses apparatus with similar structural features. Both the instant application and copending Application No. 10/399,450 claimed the steps of providing a support body (step (a) of instant claim 39 and claim 31, step (a) of copending Application No. 10/399,450); flowing a liquid of receptors or receptors building block over a support (step (b) of instant claim 39 and claim 31, step (d) of copending Application No. 10/399,450); immobilizing the receptors or receptors building block on a predetermined position on the support (step (c) of instant claim 39 and claim 31, step (e) of copending Application No. 10/399,450); repeating the flowing and immobilization steps until a

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desired receptors are immobilized on the support (step (d) of instant claim 39 and claim 31, step (f) of copending Application No. 10/399,450); contacting the support with a sample containing the analyte (step (e) of instant claim 39 and claim 31, step (g) of copending Application No. 10/399,450); and determining the analyte (step (f) of instant claim 39 and claim 31, step (h) of copending Application No. 10/399,450). Claim 37 of copending Application No. 10/399,450 claimed that the synthesis and determination are carried out in an integrated apparatus (refers to step (c) of instant claim 39). Moreover, the limitations recited in the claims of copending Application No. 10/399,450, i.e. claims 38-45, correspond to the limitations recited in the claims of the instant application, i.e. claims 40-45, 47, 48, and 50. That is the method of the instant application is generic to the presently claimed method of copending Application No. 10/399,450, or in other words, claims 39-45, 47, 48, and 50 are anticipated by claims 31 and 37-45 of copending Application No. 10/399,450. Thus, the examined claims would have been obvious over the claims of copending Application No. 10/399,450.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

My-Chau T. Tran
November 12, 2006

 11/12/06
MY-CHAU T. TRAN
PATENT EXAMINER